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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,915

04/19/2005

Motokazu Iwata

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WENDEROTH, LIND & PONACK, L.L.P.

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EXAMINER

HEINCER, LIAM J

ART UNIT

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1796

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/531,915	<b>Applicant(s)</b> IWATA ET AL.	
	<b>Examiner</b> Liam J. Heincer	<b>Art Unit</b> 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/2005 and 7/2005</u> .                                       | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement filed April 19, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Objections***

Claim 20 is objected to because of the following informalities: there is a typo in claim 20 such that it reads "one or both of these messes" rather than "one or both of these masses". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Considering Claims 1-20: Claims 1, 9, 10, 11, and 16-20 contain the phrase "aldehyde-like". It is unclear what is meant by this phrasing. For the purpose of further examination the claim is being interpreted as referring to substances with aldehyde reactivity.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bunczek et al. (US Pat. 5,192,561).

Considering Claims 1-4: Bunczek et al. teaches a composition comprising cinnamon flavoring/a substance capable of providing aldehyde (1:32-37) and further comprising aspartame/a low-molecular weight active substance, the stability of which is impaired by the effects of aldehyde (1:29-32) and gelatin (2:16-21).

Considering Claim 5-7: Bunczek et al. teaches the components as being present in a powdered form (4:5-9).

Considering Claims 8-10: Instant claims 8-10 are product-by-process claims. Product-by-process claims are evaluated by the structure that the process implies, not necessarily the process itself. As Bunczek et al. appears to provide a composition that is substantially the same as claimed in the instant claims, the claims are considered anticipated. See MPEP 2173.05.

Claims 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bunczek et al. (US Pat. 5,192,561).

Considering Claim 16: Bunczek et al. teaches mixing (6:15-20) aspartame/a low-molecular weight active substance, the stability of which is impaired by the effects of aldehyde (1:29-32) and gelatin (2:16-21).

Considering Claim 17: Bunczek et al. teaches further mixing the composition with cinnamon flavoring/a substance capable of providing aldehyde (32-37).

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Nomura et al. (WO 01/74397). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.

Considering Claims 1-4: Nomura et al. teaches a composition comprising mannitol, or starch/a substance capable of providing aldehyde (¶0027) which further comprises a low molecular weight active substance (¶0021) and L-arginine (¶0025).

Considering Claim 5-7: Nomura et al. teaches the components as being present in a powdered form (¶0020).

Considering Claims 8-10: Instant claims 8-10 are product-by-process claims. Product-by-process claims are evaluated by the structure that the process implies, not necessarily the process itself. As Nomura et al. appears to provide a composition that is substantially the same as claimed in the instant claims, the claims are considered anticipated. See MPEP 2173.05.

Claims 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Nomura et al. (WO 01/74397). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.

Considering Claim 11: Nomura et al. teaches a solution/mass comprising mannitol and L-arginine and a solution/mass comprising a low molecular weight (¶0021) active substance (¶0048).

Claims 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Nomura et al. (WO 01/74397). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.

Considering Claim 16 and 17 : Nomura et al. teaches mixing (¶0020) mannitol, or starch/a substance capable of providing aldehyde (¶0027) with a low molecular weight active substance (¶0021) and L-arginine (¶0025).

Considering Claim 20: Nomura et al. teaches preparing a solution/mass comprising mannitol and L-arginine and a solution/mass comprising a low molecular weight (¶0021) active substance (¶0048).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura et al. (WO 01/74397) as applied to claim 11 above, and further in view of Kurihara et al. (US Pat. 5,726,180). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.

Considering Claims 12-15: Nomura et al. teaches the composition of claim 11 as shown above.

Nomura et al. does not teach the masses as being in the form of granules. However, Kurihara et al. teaches forming fine granules (4:2), which can be incorporated

into a capsule or tablet (9:31-54) of the ingredients of a drug composition where the ingredients are separated (8:6-11). Nomura et al. and Kurihara et al. are combinable as they are concerned with a similar technical difficulty, namely forming stable drug compositions. It would have been obvious to a person having ordinary skill in the art at the time of invention to have formed fine granules of Kurihara et al. in the composition of Nomura et al., and the motivation to do so would have been, as Kurihara et al. suggests, it will improve the stability of the composition for a longer period of time (abstract).

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura et al. (WO 01/74397) as applied to claim 16 above, and further in view of Kurihara et al. (US Pat. 5,726,180). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.

Considering Claims 18 and 19: Nomura et al. teaches the composition of claim 16 as shown above. Nomura et al. also teaches preparing a solution/mass comprising mannitol and L-arginine and a solution/mass comprising a low molecular weight (¶0021) active substance (¶0048).

Nomura et al. does not teach the masses as being in the form of granules. However, Kurihara et al. teaches forming granules (4:2) of the ingredients of a drug composition where the ingredients are separated (8:6-11). Nomura et al. and Kurihara et al. are combinable as they are concerned with a similar technical difficulty, namely forming stable drug compositions. It would have been obvious to a person having ordinary skill in the art at the time of invention to have formed fine granules of Kurihara et al. in the composition of Nomura et al., and the motivation to do so would have been, as Kurihara et al. suggests, it will improve the stability of the composition for a longer period of time (abstract).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO Form 892.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liam J. Heincer whose telephone number is 571-270-3297. The examiner can normally be reached on Monday thru Friday 7:30 to 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/  
Supervisory Patent Examiner, Art Unit 1796  
12-Feb-08

LJH  
January 28, 2008